

REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Upon entry of this amendment, claims 17-30 will remain pending in the present application. Claims 27-29 have been withdrawn from consideration.

Claims 17, 18, 20-22, 24, 25, and 30 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,660,170 to Rajan et al. ("the '170 patent") in view of U.S. Patent No. 4,444,201 to Itoh ("the '201 patent"). In addition, claims 19 and 26 stand rejected under 35 U.S.C. § 103 as being unpatentable over the '170 patent in view of the '201 patent and in further view of U.S. Patent No. 5,551,419 to Froehlich et al. ("the '419 patent"). Finally, claim 23 stands rejected under 35 U.S.C. § 103 as being unpatentable over the '170 patent in view of the '201 patent and in further view of U.S. Patent No. 5,868,133 to DeVries et al. ("the '133 patent"). Applicant respectfully traverses these rejections for the reasons presented below.

Independent claim 17 recites a pressure support system that determines an average intrinsic positive end-expiratory pressure based on an output of the monitoring means and controls the flow of gas delivered to the subject such that the delivered pressure during at least a portion of an expiratory phase of a breathing cycle substantially corresponds to the average intrinsic positive end-expiratory pressure. Applicant respectfully submits that the '170 patent does not teach or suggest controlling the gas delivered during at least a portion of an expiratory phase of a breathing cycle in this manner.

The '170 patent teaches providing a flow of gas during inspiration so that the pressure at the end of the inspiration phase has a peak inspiratory pressure (PIP) level and providing the flow of gas during expiration so that the pressure at the end of the expiration phase has a positive end expiratory pressure (PEEP) level. Applicant again maintains that the '170 patent does not teach or suggest determining the PEEP level based on an average intrinsic positive end-expiratory pressure.

The Examiner correctly notes that the '170 patent teaches determining an "opening pressure", which is a pressure at which the alveoli begin to open and is referred to as " P_o ". The pressure provided to the patient during exhalation by the therapy system can be controlled to correspond to opening pressure P_o so that the patient receives a pressure sufficient to open the alveoli. The Examiner appears to take the position that P_o is determined in the '170 patent based on an average intrinsic positive end-expiratory pressure (PEEP). Applicant respectfully submits, however, that this is not the case. The '170 patent teaches a relatively elaborate technique for determining P_o , which is described in columns 6-8 of that patent with reference to FIGS. 2-5 and which is not based on an average the PEEPs.

In short, the '170 patent teaches determining P_o by providing the patient with a test pressure or series of test pressures and monitoring the resulting flow. A flow versus pressure curve is plotted to monitor how the flow changed as a result of increasing the pressure. FIG. 4 illustrates a flow v. pressure waveform, which is referred to as curve 26. The flow v. pressure waveform is monitored for any relatively abrupt increases in flow along the pressure scale. The abrupt increases in flow are referred to as an "inflection region" and are identified as regions 28 and 30 in FIG. 4. These abrupt increases or inflection regions indicate opening of the patient's alveoli as a result of the lungs having reached an "opening pressure". See column 6, lines 53-67, of the '170 patent.

Of concern in the '170 patent is how to generate the flow v. pressure waveform (curve 26). The '170 patent appears to teach at least two techniques. One technique is to simply start at a low pressure, measure the flow, and increase the pressure while continuing to measure the flow. This technique will produce the flow v. pressure waveform (curve 26), but it will be more of a "snapshot", and, as a result, could include one-time aberrations. A flow v. pressure waveform that better represents the actual condition of the lungs, i.e., avoids such aberrations, is to provide a series of identical pulses in which the pressure starts low and goes high during each pulse, while measuring the patient flow during each pulse. FIG. 2 illustrates a series of such pulses (18, 20, 22). If these pressure pulses are identical, the flow at each associated pressure can

be averaged to produce the flow v. pressure waveform (curve 26), where the flow on the vertical scale is an average flow.

It can be appreciated from the foregoing summary of the technique used by the '170 patent to determine opening pressure P_o , that nothing in this technique includes determining an average positive end expiratory pressure. At best, the '170 patent teaches determining an average flow at each pressure from a series of pressure pulses. However, those skilled in the art can readily appreciate that averaging the flow measurement taken, for example, when a pressure of 5 cmH₂O was delivered to the patient in each pressure pulse, is vastly different from determining an average PEEP.

In the paragraph beginning on page 3, line 21, of the March 19, 2008 Office Action, the Examiners states, “[the '170 patent] discloses averaging the respiratory gas flow to determine the ‘opening pressure’ but is silent with regards to averaging the PEEP level for each inspiration pulse.” Applicant respectfully submits that claim 17 has been amended to clarify that the average intrinsic positive end-expiratory pressure corresponds to the average over a plurality of breathing cycles, and not the average PEEP level for each inspiration pulse or breath. As a result of the this clarification, the Examiner’s discussion of what is “inherent” in the '170 patent becomes moot.

The Examiner cites the '201 patent for the proposition that it was known to average stored PEEP pressures. While the applicant will not address the merits of this conclusion for the sake of brevity, applicant does note that the '170 patent uses a specific technique for detecting the opening pressure P_o , and this technique, as explained above, does not use PEEP to determine the opening pressure (it uses flow or average flow). Thus, there simply is no need to calculate an average PEEP level in practicing the '170 patent. As a result, one skilled in the art would not consider it obvious to apply the PEEP averaging function of the '201 patent with the opening pressure determining or pressure control technique of the '170 patent.

Independent claim 30 is a method claims that is generally similar to independent apparatus claim 17. Thus, the distinctions between claim 17 and the cited references are equally applicable to claim 30.

The additional citations to the '419 patent and the '133 patent are provided to establish the existence of features recited in dependent claims. These secondary references, however, do not teach or suggest the features of independent claims 17 or 30 missing from the primary references as discussed above.

For the reasons presented above, applicant respectfully submits that independent claims 17 and 30 are not anticipated or rendered obvious by the cited references. In addition, claims 18-26 are also not anticipated or rendered obvious due to their dependency from independent claim 17. Accordingly, applicant respectfully requests that the above rejections of claims 17-26 and 30 be withdrawn.

This response is being filed within the three-month statutory response period which expires on June 19, 2008. In addition, no additional claim fees are believed to be required as a result of the above amendments to the claims. Nevertheless, the Commissioner is authorized to charge any fee required under 37 C.F.R. §§ 1.16 or 1.17 to deposit account no. 50-0558.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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